RULE

Department of Health and Hospitals
Office of Public Health

Establishment of an Office of Research Integrity

There is hereby established within the Office of Public Health (OPH) an Office of Research Integrity (ORI) to comply with federal regulation 42 CFR Part 50, Subpart A. The complete policies and procedures of the OPH-ORI have been accepted as complying with the federal guidelines by the United States Department of Health and Human Services, Office of Research Integrity and are as follows.

I. Introduction

A. General Policy

The Louisiana Office of Public Health is fully and unequivocally dedicated to maintaining the highest of scientific standards in its patient care, public health and health-related research activities. These standards include adherence to professional health care ethics, as stated in health care worker professional conduct or ethics codes and/or in state law. All such ethics include maintenance of scientific integrity, preventing misconduct in research, doing no harm to anyone whose health care is in the trust of the Louisiana Office of Public Health, and supporting in good faith those persons, who report suspected or known activities contrary to these stated ethics guidelines.

B. Scope

This policy and the associated procedures apply to all individuals at the Louisiana Office of Public Health engaged in research that is supported by or for which support is requested from PHS. The PHS regulation at 42 CFR Part 50, Subpart A applies to any research, research-training or research-related grant or cooperative agreement with PHS. This policy applies to any person paid by, under the control of, or affiliated with the institution, such as scientists, trainees, technicians and other staff members, students, fellows, guest researchers, or collaborators at the Louisiana Office of Public Health.

The policy and associated procedures will normally be followed when an allegation of possible misconduct in science is received by an institutional official. Particular circumstances in an individual case may dictate variation from the normal procedure deemed in the best interests of the Louisiana Office of Public Health and PHS. Any change from normal procedures also must ensure fair treatment to the subject of the inquiry or investigation. Any significant variation should be approved in advance by the research integrity officer of the Louisiana Office of Public Health.

II. Definitions

A. *Allegation*any written or oral statement or other indication of possible scientific misconduct made to an institutional official.

B. *Complainant*a person who makes an allegation of scientific misconduct.

C. *Conflict of Interest*the real or apparent interference of one person's interests with the interests of another person, where potential bias may occur due to prior or existing personal or professional relationships.

D. *Deciding Official*the institutional official who makes final determinations on allegations of scientific misconduct and any responsive institutional actions. The deciding official will not be the same individual as the research integrity officer and should have no direct prior involvement in the institution's inquiry, investigation or allegation assessment.

E. *Goodfaith Allegation*an allegation made with the honest belief that scientific misconduct may have occurred. An allegation is not in good faith if it is made with reckless disregard for or willful ignorance of facts that would disprove the allegation.

F. *Inquiry*gathering information and initial fact-finding to determine whether an allegation or apparent instance of scientific misconduct warrants an investigation.

G. *Investigation*the formal examination and evaluation of all relevant facts to determine if misconduct has occurred, and, if so, to determine the responsible person and the seriousness of the misconduct.

H. *ORI*the Office of Research Integrity, the office within the U. S. Department of Health and Human Services (DHHS) that is responsible for the scientific misconduct and research integrity activities of the U.S. Public Health Service.

I. *PHS*the U.S. Public Health Service, an operating component of the DHHS.

J. *PHS' Regulation*the Public Health Service regulation establishing standards for institutional inquiries and investigations into allegations of scientific misconduct, which is set forth at 42 CFR Part 50, Subpart A, entitled "Responsibility of PHS Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science..

K. *PHS Support*PHS grants, contracts, or cooperative agreements or applications therefore.

L. *Research Integrity Officer*the institutional official responsible for assessing allegations of scientific misconduct and determining when such allegations warrant inquiries and for overseeing inquiries and investigations.

M. *Research Record*any data, document, computer file, computer diskette, or any other written or non-written account or object that reasonably may be expected to provide evidence or information regarding the proposed, conducted or reported research that constitutes the subject of an allegation of scientific misconduct. A research record includes, but is not limited to, grant or contract applications, whether funded or unfunded; grant or contract progress and other reports; laboratory notebooks; notes; correspondence; videos, photographs; X-ray film; slides; biological materials; computer files and printouts; manuscripts and publications; equipment use logs; laboratory procurement records; animal facility records; human and animal subject protocols; consent forms; medical charts and patient research files.

N. *Respondent*the person against whom an allegation of scientific misconduct is directed or the person whose actions are the subject of the inquiry or investigation. There can be more than one respondent in any inquiry or investigation.

O. *Retaliation*any action that adversely affects the employment or other institutional status of an individual that is taken by an institution or an employee because the individual has in good faith, made an allegation of scientific misconduct or of inadequate institutional response thereto or has cooperated in good faith with an investigation of such allegation.

P. *Scientific Misconduct or Misconduct in Science*fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data.

III. Rights and Responsibilities

A. Research Integrity Officer

The deciding official will appoint the research integrity officer who will have primary responsibility for implementation of the procedures set forth in this document. The research integrity officer will be an institutional official who is well qualified to handle the procedural requirements involved and is sensitive to the varied demands made on those who conduct research, those who are accused of misconduct, and those who report apparent misconduct in good faith.

The research integrity officer will appoint the inquiry and investigation committees and ensure that necessary and appropriate expertise is secured to carry out a thorough and authoritative evaluation of the relevant evidence in an inquiry or investigation. The research integrity officer will attempt to ensure that confidentiality is maintained.

The research integrity officer will assist inquiry and investigation committees and all institutional personnel in complying with these procedures and with applicable standards imposed by government or external funding sources. The research integrity officer is also responsible for maintaining files of all documents and evidence and for the confidentiality and the security of the files.

The research integrity officer will report to ORI as required by regulation and keep ORI apprised of any developments during the course of the inquiry or investigation that may affect current or potential DHHS funding for the individual(s) under investigation or that PHS needs to know to ensure appropriate use of Federal funds and otherwise protect the public interest.

B. Complainant

The complainant will have an opportunity to testify before the inquiry and investigation committees, to review portions of the inquiry and investigation reports pertinent to his/her allegations or testimony, to be informed of the results of the inquiry and investigation, and to be protected from retaliation. Also, if the research integrity officer has determined that the complainant may be able to provide pertinent information on any portions of the draft report, these portions will be given to the complainant for comment.

The complainant is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with an inquiry or investigation.

C. Respondent

The respondent will be informed of the allegations when an inquiry is opened and notified in writing of the final determinations and resulting actions. The respondent will also have the opportunity to be interviewed by and present evidence to the inquiry and investigation committees, to review the draft inquiry and investigation reports, and to have the advice of counsel.

The respondent is responsible for maintaining confidentiality and cooperating with the conduct of an inquiry or investigation. If the respondent is not found guilty of scientific misconduct, he or she has the right to receive institutional assistance in restoring his or her reputation.

D. Deciding Official

The deciding official will receive the inquiry and/or investigation report and any written comments made by the respondent or the complainant on the draft report. The deciding official will consult with the research integrity officer or other appropriate officials and will determine whether to conduct an investigation, whether misconduct occurred, whether to impose sanctions, or whether to take other appropriate administrative actions [see Section X].

IV. General Policies and Principles

A. Responsibility to Report Misconduct

All employees or individuals associated with the Louisiana Office of Public Health should report observed, suspected, or apparent misconduct in science to the research integrity officer. If an individual is unsure whether a suspected incident falls within the definition of scientific misconduct, he or she may call the research integrity officer at (504) 568-5048 or LINC 621-5048 or 1-800-256-4609 to discuss the suspected misconduct informally. If the circumstances described by the individual do not meet the definition of scientific misconduct, the research integrity officer will refer the individual or allegation to other offices or officials with responsibility for resolving the problem.

At any time, an employee may have confidential discussions and consultations about concerns of possible misconduct with the research integrity officer and will be counseled about appropriate procedures for reporting allegations.

B. Protecting the Complainant

The research integrity officer will monitor the treatment of individuals who bring allegations of misconduct or of inadequate institutional response thereto, and those who cooperate in inquiries or investigations. The research integrity officer will ensure that these persons will not be retaliated against in the terms and conditions of their employment or other status at the institution and will review instances of alleged retaliation for appropriate action.

Employees should immediately report any alleged or apparent retaliation to the research integrity officer.

Also, the institution will protect the privacy of those who report misconduct in good faith to the maximum extent possible. For example, if the complainant requests anonymity, the institution will make an effort to honor the request during the allegation assessment or inquiry within applicable policies and regulations and state and local laws, if any. The complainant will be advised that if the matter is referred to an investigation committee and the complainant's testimony is required, anonymity may no longer be guaranteed. Institutions are required to undertake diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations.

C. Protecting the Respondent

Inquiries and investigations will be conducted in a manner that will ensure fair treatment to the respondent(s) in the inquiry or investigation and confidentiality to the extent possible without compromising public health and safety or thoroughly carrying out the inquiry or investigation.

Institutional employees accused of scientific misconduct may consult with legal counsel or a non-lawyer personal adviser (who is not a principal or witness in the case) to seek advice and may bring the counsel or personal adviser to interviews or meetings on the case.

D. Cooperation with Inquiries and Investigations. Institutional employees will cooperate with the research integrity officer and other institutional officials in the review of allegations and the conduct of inquiries and investigations. Employees have an obligation to provide relevant evidence to the research integrity officer or other institutional officials on misconduct allegations.

E. Preliminary Assessment of Allegations. Upon receiving an allegation of scientific misconduct, the research integrity officer will immediately assess the allegation to determine whether there is sufficient evidence to warrant an inquiry, whether PHS support or PHS applications for funding are involved, and whether the allegation falls under the PHS definition of scientific misconduct.

V. Conducting the inquiry

A. Initiation and Purpose of the Inquiry. Following the preliminary assessment, if the research integrity officer determines that the allegation provides sufficient information to allow specific follow-up, involves PHS support, and falls under the PHS definition of scientific misconduct, he or she will immediately initiate the inquiry process. In initiating the inquiry, the research integrity officer should identify clearly the original allegation and any related issues that should be evaluated. The purpose of the inquiry is to make a preliminary evaluation of the available evidence and testimony of the respondent, complainant, and key witnesses to determine whether there is sufficient evidence of possible scientific misconduct to warrant an investigation. The purpose of the inquiry is not to reach a final conclusion about whether misconduct definitely occurred or who was responsible. The findings of the inquiry must be set forth in an inquiry report.

B. Sequestration of the Research Records. After determining that an allegation falls within the definition of misconduct in science and involves PHS funding, the research integrity officer must ensure

that all original research records and materials relevant to the allegation are immediately secured. The research integrity officer may consult with ORI for advice and assistance in this regard.

C. Appointment of the Inquiry Committee

The research integrity officer, in consultation with other institutional officials as appropriate, will appoint an inquiry committee and committee chair within 10 working days of the initiation of the inquiry. The inquiry committee should consist of individuals who do not have real or apparent conflicts of interest in the case, are unbiased, and have the necessary expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the inquiry. These individuals may be scientists, subject matter experts, administrators, lawyers, or other qualified persons, and they may be from inside or outside the institution.

The research integrity officer will notify the respondent of the proposed committee membership in 10 working days. If the respondent submits a written objection to any appointed member of the inquiry committee or expert based on bias or conflict of interest within five days, the research integrity officer will determine whether to replace the challenged member or expert with a qualified substitute.

D. Charge to the Committee and the First Meeting

The research integrity officer will prepare a charge for the inquiry committee that describes the allegations and any related issues identified during the allegation assessment and states that the purpose of the inquiry is to make a preliminary evaluation of the evidence and testimony of the respondent, complainant, and key witnesses to determine whether there is sufficient evidence of possible scientific misconduct to warrant an investigation as required by the PHS regulation. The purpose is not to determine whether scientific misconduct definitely occurred or who was responsible.

At the committee's first meeting, the research integrity officer will review the charge with the committee, discuss the allegations, any related issues, and the appropriate procedures for conducting the inquiry, assist the committee with organizing plans for the inquiry, and answer any questions raised by the committee. The research integrity officer and institutional counsel will be present or available throughout the inquiry to advise the committee as needed.

E. Inquiry Process. The inquiry committee will normally interview the complainant, the respondent, and key witnesses as well as examining relevant research records and materials. Then the inquiry committee will evaluate the evidence and testimony obtained during the inquiry. After consultation with the research integrity officer and institutional counsel, the committee members will decide whether there is sufficient evidence of possible scientific misconduct to recommend further investigation. The scope of the inquiry does not include deciding whether misconduct occurred or conducting exhaustive interviews and analyses.

VI. The Inquiry Report

A. Elements of the Inquiry Report. A written inquiry report must be prepared that states the name and title of the committee members and experts, if any; the allegations; the PHS support; a summary of the inquiry process used; a list of the research records reviewed; summaries of any interviews; a description of the evidence in sufficient detail to demonstrate whether an investigation is warranted or not; and the committee's determination as to whether an investigation is recommended and whether any other actions should be taken if an investigation is not recommended. Institutional counsel will review the report for legal sufficiency.

B. Comments on the Draft Report by the Respondent and the Complainant. The research integrity officer will provide the respondent with a copy of the draft inquiry report or a summary of the inquiry findings for comment and rebuttal and will provide the complainant, if he or she is identifiable, with portions of the draft inquiry report that address the complainant's role and opinions in the investigation.

1. Confidentiality. The research integrity officer may establish reasonable conditions for review to protect the confidentiality of the draft report.

2. Receipt of Comments. Within 14 calendar days of their receipt of the draft report, the complainant and respondent will provide their comments, if any, to the inquiry committee. Any comments that the complainant or respondent submits on the draft report will become part of the final inquiry report and record. Based on the comments, the inquiry committee may revise the report as appropriate.

C. Inquiry Decision and Notification.

1. Decision by Deciding Official. The Research Integrity Office will transmit the final report and any comments to the Deciding Official, who will make the determination of whether findings from the inquiry provide sufficient evidence of possible scientific misconduct to justify conducting an investigation. The inquiry is completed when the Deciding Official makes this determination, which will be made within 60 days of the first meeting of the inquiry committee. Any extension of this period will be based on good cause and recorded in the inquiry file.

2. Notification. The research integrity officer will notify both the respondent and the complainant in writing of the Deciding Official's decision of whether to proceed to an investigation and will remind

them of their obligation to cooperate in the event an investigation is opened. The research integrity officer will also notify all appropriate institutional officials of the Deciding Official's decision.

D. Time Limit for Completing the Inquiry Report. The inquiry committee will normally complete the inquiry and submit its report in writing to the research integrity officer no more than 60 calendar days following its first meeting, unless the research integrity officer approves an extension for good cause. If the research integrity officer approves an extension, the reason for the extension will be entered into the records of the case and the report. The respondent also will be notified of the extension.

VII. Conducting the Investigation

A. Purpose of the Investigation. The purpose of the investigation is to explore in detail the allegations, to examine the evidence in depth, and to determine specifically whether misconduct has been committed, by whom, and to what extent. The investigation will also determine whether there are additional instances of possible misconduct that would justify broadening the scope beyond the initial allegations. This is particularly important where the alleged misconduct involves clinical trials or potential harm to human subjects or the general public or if it affects research that forms the basis for public policy, clinical practice, or public health practice. The findings of the investigation will be set forth in an investigation report.

B. Sequestration of the Research Records. The research integrity officer will immediately sequester any additional pertinent research records that were not previously sequestered during the inquiry. This sequestration should occur before or at the time the respondent is notified that an investigation has begun. The need for additional sequestration of records may occur for any number of reasons, including the institution's decision to investigate additional allegations not considered during the inquiry stage or the identification of records during the inquiry process that had not been previously secured. The procedures to be followed for sequestration during the investigation are the same procedures that apply during the inquiry.

C. Appointment of the Investigation Committee

The research integrity officer, in consultation with other institutional officials as appropriate, will appoint an investigation committee and the committee chair within 10 working days of the notification to the respondent that an investigation is planned or as soon thereafter as practicable. The investigation committee should consist of at least three individuals who do not have real or apparent conflicts of interest in the case, are unbiased, and have the necessary expertise to evaluate the evidence and issues related to the allegations, interview the principals and key witnesses, and conduct the investigation. These individuals may be scientists, administrators, subject matter experts, lawyers, or other qualified persons, and they may be from inside or outside the institution. Individuals appointed to the investigation committee may also have served on the inquiry committee.

The research integrity officer will notify the respondent of the proposed committee membership within five working days. If the respondent submits a written objection to any appointed member of the investigation committee or expert, the research integrity officer will determine whether to replace the challenged member or expert with a qualified substitute.

D. Charge to the Committee and the First Meeting

1. Charge to the Committee

The research integrity officer will define the subject matter of the investigation in a written charge to the committee that describes the allegations and related issues identified during the inquiry, defines scientific misconduct, and identifies the name of the respondent. The charge will state that the committee is to evaluate the evidence and testimony of the respondent, complainant, and key witnesses to determine whether, based on a preponderance of the evidence, scientific misconduct occurred and, if so, to what extent, who was responsible, and its seriousness.

During the investigation, if additional information becomes available that substantially changes the subject matter of the investigation or would suggest additional respondents, the committee will notify the research integrity officer, who will determine whether it is necessary to notify the respondent of the new subject matter or to provide notice to additional respondents.

2. The First Meeting. The research integrity officer, with the assistance of institutional counsel, will convene the first meeting of the investigation committee to review the charge, the inquiry report and the prescribed procedures and standards for the conduct of the investigation, including the necessity for confidentiality and for developing a specific investigation plan. The investigation committee will be provided with a copy of these instructions and, where PHS funding is involved, the PHS regulation.

E. Investigation Process

The investigation committee will be appointed and the process initiated within 30 days of the completion of the inquiry, if findings from that inquiry provide a sufficient basis for conducting an investigation.

The investigation will normally involve examination of all documentation including, but not necessarily limited to, relevant research records, computer files, proposals, manuscripts, publications,

correspondence, memoranda, and notes of telephone calls. Whenever possible, the committee should interview the complainant(s), the respondent(s), and other individuals who might have information regarding aspects of the allegations. Interviews of the respondent should be tape recorded or transcribed. All other interviews should be transcribed, tape recorded, or summarized. Summaries or transcripts of the interviews should be prepared, provided to the interviewed party for comment or revision, and included as part of the investigatory file.

VIII. The Investigation Report

A. Elements of the Investigation Report. The final report submitted to ORI must describe the policies and procedures under which the investigation was conducted, describe how and from whom information relevant to the investigation was obtained, state the findings, and explain the basis for the findings. The report will include the actual text or an accurate summary of the views of any individual(s) found to have engaged in misconduct as well as a description of any sanctions imposed and administrative actions taken by the institution.

B. Comments on the Draft Report

1 . Respondent. The research integrity officer will provide the respondent with a copy of the draft investigation report for comment and rebuttal. The respondent will be allowed 30 days to review and comment on the draft report. The respondent's comments will be attached to the final report. The findings of the final report should take into account the respondent's comments in addition to all the other evidence.

2. Complainant. The research integrity officer will provide the complainant, if he or she is identifiable, with those portions of the draft investigation report that address the complainant's role and opinions in the investigation. The report should be modified, as appropriate, based on the complainant's comments.

3. Institutional Counsel. The draft investigation report will be transmitted to the institutional counsel for a review of its legal sufficiency. Comments should be incorporated into the report as appropriate.

4. Confidentiality. In distributing the draft report, or portions thereof, to the respondent and complainant, the research integrity officer will inform the recipient of the confidentiality under which the draft report is made available and may establish reasonable conditions to ensure such confidentiality. For example, the research integrity officer may request the recipient to sign a confidentiality statement or to come to his or her office to review the report.

C. Institutional Review and Decision

Based on a preponderance of the evidence, the deciding official will make the final determination whether to accept the investigation report, its findings, and the recommended institutional actions. If this determination varies from that of the investigation committee, the deciding official will explain in detail the basis for rendering a decision different from that of the investigation committee in the institution's letter transmitting the report to ORI. The deciding official's explanation should be consistent with the PHS definition of scientific misconduct, the institution's policies and procedures, and the evidence reviewed and analyzed by the investigation committee. The deciding official may also return the report to the investigation committee with a request for further fact–finding or analysis. The deciding official's determination, together with the investigation committee's report, constitutes the final investigation report for purposes of ORI review.

When a final decision on the case has been reached, the research integrity officer will notify both the respondent and the complainant in writing. In addition, the deciding official will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals in which falsified reports may have been published, collaborators of the respondent in the work, or other relevant parties should be notified of the outcome of the case. The research integrity officer is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.

D. Transmittal of the Final Investigation Report to ORI. After comments have been received and the necessary changes have been made to the draft report, the investigation committee should transmit the final report with attachments, including the respondent's and complainant's comments, to the Deciding Official, through the research integrity officer.

E. Time Limit for Completing the Investigation Report. An investigation should ordinarily be completed with 120 days of its initiation, with the initiation being defined as the first meeting of the investigation committee. This includes conducting the investigation, preparing the report of findings, making the draft report available to the subject of the investigation for comment, submitting the report to the deciding official for approval, and submitting the report to the ORI.

IX. Requirements for Reporting to ORI

A. An institution's decision to initiate an investigation must be reported in writing to the Director, ORI, on or before the date the investigation begins. At a minimum, the notification should include the name of the person(s) against whom the allegations have been made, the general nature of the allegation

as it relates to the PHS definition of scientific misconduct, and the PHS applications or grant number(s) involved. ORI must also be notified of the final outcome of the investigation and must be provided with a copy of the investigation report. Any significant variations from the provisions of the institutional policies and procedures should be explained in any reports submitted to ORI.

B. If an institution plans to terminate an inquiry or investigation for any reason without completing all relevant requirements of the PHS regulation, the Research Integrity Officer will submit a report of the planned termination to ORI, including a description of the reasons for the proposed termination.

C. If the institution determines that it will not be able to complete the investigation in 120 days, the research integrity officer will submit to ORI a written request for an extension that explains the delay, reports on the progress to date, estimates the date of completion of the report, and describes other necessary steps to be taken. If the request is granted, the research integrity officer will file periodic progress reports as requested by the ORI.

D. When PHS funding or applications for funding are involved and an admission of scientific misconduct is made, the Research Integrity Office will contact ORI for consultation and advice. Normally, the individual making the admission will be asked to sign a statement attesting to the occurrence and extent of misconduct. When the case involves PHS funds, the institution cannot accept an admission of scientific misconduct as a basis for closing a case or not undertaking an investigation without prior approval from ORI.

E. The research integrity officer will notify ORI at any stage of the inquiry or investigation if

1. there is an immediate health hazard involved;
2. there is an immediate need to protect Federal funds or equipment;
3. there is an immediate need to protect the interests of the person(s) making the allegations or of the individual(s) who is the subject of the allegations as well as his/her co-investigators and associates, if any;
4. it is probable that the alleged incident is going to be reported publicly; or
5. the allegation involves a public health sensitive issue, e.g., a clinical trial; or
6. there is a reasonable indication of possible criminal violation. In this instance, the institution must inform ORI within 24 hours of obtaining that information.

X. Institutional Administrative Actions

Louisiana Office of Public Health will take appropriate administrative actions against individuals when an allegation of misconduct has been substantiated.

If the Deciding Official determines that the alleged misconduct is substantiated by the findings, he or she will decide on the appropriate actions to be taken, after consultation with the research integrity officer. The actions may include:

1. withdrawal or correction of all pending or published abstracts and papers emanating from the research where scientific misconduct was found;
2. removal of the responsible person from the particular project, letter of reprimand, special monitoring of future work, probation, suspension, salary reduction, or initiation of steps leading to possible rank reduction or termination of employment;
3. restitution of funds as appropriate.

XI. Other Considerations

A. Termination of Institutional Employment or Resignation Prior to Completing Inquiry or Investigation

The termination of the respondent's institutional employment, by resignation or otherwise, before or after an allegation of possible scientific misconduct has been reported, will not preclude or terminate the misconduct procedures.

If the respondent, without admitting to the misconduct, elects to resign his or her position prior to the initiation or an inquiry, but after an allegation has been reported, or during an inquiry or investigation, the inquiry or investigation will proceed. If the respondent refuses to participate in the process after resignation, the committee will use its best efforts to reach a conclusion concerning the allegations, noting in its report the respondent's failure to cooperate and its effect on the committee's review of all the evidence.

B. Restoration of the Respondent's Reputation. If the institution finds no misconduct and ORI concurs, after consulting with the respondent, the research integrity officer will undertake reasonable efforts to restore the respondent's reputation. Depending on the particular circumstances, the research integrity officer should consider notifying those individuals aware of or involved in the investigation of the final outcome, publicizing the final outcome in forums in which the allegation of scientific misconduct was previously publicized, or expunging all reference to the scientific misconduct allegation from the respondent's personnel file. Any institutional actions to restore the respondent's reputation must first be approved by the Deciding Official.

C. Protection of the Complainant and Others. Regardless of whether the institution or ORI determines that scientific misconduct occurred, the research integrity officer will undertake reasonable

efforts to protect complainants who made allegations of scientific misconduct in good faith and others who cooperate in good faith with inquiries and investigations of such allegations. Upon completion of an investigation, the Deciding Official will determine, after consulting with the complainant, what steps, if any, are needed to restore the position or ORI reputation of the complainant. The research integrity officer is responsible for implementing any steps the Deciding Official approves. The research integrity officer will also take appropriate steps during the inquiry and investigation to prevent any retaliation against the complainant.

D. Allegations not made in Good Faith. If relevant, the Deciding Official will determine whether the complainant's allegations of scientific misconduct were made in good faith. If an allegation was not made in good faith, the Deciding Official will determine whether any administrative action should be taken against the complainant.

E. Interim Administrative Actions. Institutional officials will take interim administrative actions, as appropriate, to protect federal funds and ensure that the purposes of the federal financial assistance are carried out.

XII. Record Retention

After completion of a case and all ensuing related actions, the research integrity officer will prepare a complete file, including the records of any inquiry or ORI investigation and copies of all documents and other materials furnished to the research integrity officer or ORI committees. The research integrity officer will keep the file for three years after completion of the case to permit later assessment of the case. ORI or other authorized DHHS personnel will be given access to the records upon request.

In accordance with the policies and procedures of the OPH–ORI the state health officer will serve as the deciding official. Also in accordance with the policies and procedures of the OPH–ORI the state health officer will appoint the research integrity officer, who will serve as such until he or she is relieved of that responsibility by the state health officer. The research integrity officer will be an official of OPH, who is well qualified to handle the procedural requirements involved and is sensitive to the varied demands made on those who conduct research, those who are accused of misconduct, and those who report in good faith apparent misconduct.

Bobby P. Jindal
Secretary

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